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09/930,104	08/14/2001	Allan Leslie Friedman	2640/1G826US1	9867

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EXAMINER	
WEST, JEFFREY R	
ART UNIT	**PAPER NUMBER**
2857	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

EJC

Office Action Summary	Application No.	Applicant(s)	
	09/930,104	FRIEDMAN ET AL.	
	Examiner	Art Unit	
	Jeffrey R. West	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-21 and 23-47* is/are pending in the application.

4a) Of the above claim(s) *33-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-21,23-32,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

On page 1, reference is made to Provisional Application 60/241,888 as "having the same title as the present invention" while Provisional Application 60/241,888 is titled, "METHOD FOR DIFFERENTIATING BETWEEN GUNKED AND CRACKED ULTRASONICALLY TUNED BLADES".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 46 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 46 and 47 further limit their respective parent claims to specify that "the comparing step is performed continuously". The specification, however, does not contain sufficient support for such a limitation but instead only describes determining

impedance magnitudes at discrete times for comparison as opposed to a continuous comparison.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4, 5, 7-16, 20, 21, and 23-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, because it attempts to further limit parent claim 1 to include "obtaining the impedance magnitude data and impedance phase data for at least two drive levels over a prescribed range". Parent claim 1, however, already includes a limitation for "applying a drive signal having an initial drive current level and an initial drive voltage level". Therefore, it is unclear to one having ordinary skill in the art whether the "at least two drive levels" in claim 4 include the "drive signal" in claim 1, or if these drive levels correspond to different signals. It is further unclear to one having ordinary skill in the art as to whether the "at least two drive levels" in claim 4 includes the "initial drive current level" and "initial drive voltage level" in claim 1, or if these drive levels correspond to different levels.

Claim 20 is considered to be vague and indefinite for reasons similar to those presented with respect to claim 4.

Claim 20 is also considered to be vague and indefinite because it further limits "said obtaining step" of claim 17 while claim 17 comprises two separate obtaining steps.

Claim 7 is considered to be vague and indefinite because it further limits parent claim 4 to include "displaying a first message on the display, if impedance magnitude data obtained at a lower drive level reveals a minimum impedance magnitude which is less than a minimum impedance magnitude obtained at a higher drive level".

Similar to the rejection presented above with respect to claim 4, it is unclear to one having ordinary skill in the art as to what level "a lower drive level" refers. Specifically, since parent claim 4 presents "at least two drive levels" and parent claim 1 presents "a drive signal having an initial drive current level and an initial drive voltage level", it is unclear to one having ordinary skill in the art whether the "lower drive level" refers to one of the previously presented drive signals and/or levels, or refers to a different level completely.

It is also unclear as to what the "lower drive level" is lower than. Specifically, it is unclear to one having ordinary skill in the art whether the "lower drive level" is a drive level that is lower than the "drive signal" of claim 1, the "drive current level" of claim 1, the "drive voltage level" of claim 1, or one of the "at least two drive levels" of claim 4.

Claim 23 is considered to be vague and indefinite for reasons similar to those presented with respect to claim 7.

Claims 5, 8-16, 21, and 24-32 are rejected under 35 U.S.C. 112, second paragraph, because they incorporate the lack of clarity present in their respective parent claims.

Claims 29 and 30 are also rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite because they refer to, "all measured impedance magnitudes" while none of the magnitudes presented in parent claims 17, 20, and 23 are defined as being "measured" and therefore it is unclear to one having ordinary skill in the art as to what values "all measured impedance magnitudes" refers.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 1, 2, 4, 17, 18, and 20, as may best be understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,042,460 to Sakurai et al. in view of JP Patent No. 06-003305 to Senda et al.

Sakurai discloses an ultrasonic treating apparatus with a device for inhibiting drive when the ultrasonic element is determined to be defective comprising applying a drive signal to an ultrasonic hand piece/blade using an ultrasonic generator

including initial current and voltage drive levels (column 4, lines 17-30), obtaining impedance magnitude data for the hand piece/blade while continuously driving the hand piece/blade with the drive signal (column 4, lines 31-34) comparing the impedance data to a known value to determine whether the impedance data is within acceptable limits (column 4, lines 35-39) and if the impedance is within acceptable limits, displaying a message on a display of the generator (column 4, lines 40-42).

As noted above, the invention of Sakurai teaches many of the features of the claimed invention and while the invention of Sakurai does teach determining incorrect operation of transducer device, Sakurai discloses determining incorrect operation due to degradation of the device rather than determining a physical defect that causes the incorrect operation.

Senda teaches a method for non-destructively inspecting a piezoelectric element for a micro-crack comprising obtaining impedance data for a known/ideal element (0013, lines 1-4) applying a drive signal for exciting the piezoelectric element over a predetermined frequency range and obtaining impedance magnitude and impedance phase data of the tested element (0021, lines 1-13), at a plurality current and voltage excitation levels (0010), and comparing the impedance of the element under test to the known element impedance data to determine the correctness of operation (0021, line 13 to 0022, line 7 and 0028). Senda also teaches comparing a magnitude of a lowest impedance (i.e. impedance at resonance) (0019) to the expected waveform to determine non-linearity (0010, 0025, and 0028).

It would have been obvious to one having ordinary skill in the art to modify the invention of Sakurai to teach a method for determining a crack in the device as compared to a known/ideal device, as taught by Senda, because the combination would have provided a method for determining the occurrence of a physical defect thereby allowing the user to correctly diagnose and correct the problem and, as suggested by Senda, provided precise diagnostics quickly, automatically, and without destroying the device under test (0005-0007).

Although the invention of Sakurai and Senda discloses performing the comparison to determine a crack in the transducer rather than the blade itself, since the blade and the transducer are attached a change in impedance due to a crack in the blade would also correspond to the change in impedance observed by the current method (See, for example, page 4, lines 7-16 of the Background of the instant invention that describes the grouped frequency response of the transducer and blade and the correlation between the electric parameters of the transducer and the blade response). Therefore, the combination of Sakurai and Senda operates in a method that determines the change in impedance indicating a crack in the transducer or the connected blade.

8. Claims 3, 5, 19, and 21, as may best be understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai in view of Senda and further in view of U.S. Patent No. 6,019,775 to Sakurai (Sakurai '775).

As noted above the invention of Sakurai and Senda teaches many of the features of the claimed invention including exciting the hand piece across a predefined frequency range and obtaining impedance data at a plurality of excitation levels, but does specify that the frequency range be from 50 to 60 kHz or that the excitation levels be in the range of 5mA to 50mA.

Sakurai '775 teaches an ultrasonic operation apparatus for performing treatment through utilization of an ultrasonic oscillator comprising a handpiece, serving as a surgical tool, and an apparatus body including a power source unit for supplying electric power to the handpiece (abstract). Sakurai '775 teaches that the handpiece includes a signal generating unit for generating a signal corresponding to a resonant frequency inherent in the ultrasonic element and the probe (abstract). Sakurai '775 also teaches that in ultrasonic surgery tools the oscillator is designed to generate a resonant frequency corresponding to the specific handpiece (column 1, lines 31-47) as well as that the excitation current of the specific handpiece varies based upon the oscillator employed (column 9, lines 41-56).

It would have been obvious to one having ordinary skill in the art to modify the invention of Sakurai and Senda to include sweeping across a predetermined frequency range of 50 to 60 kHz and exciting the handpiece at a current in the range of 5mA to 50mA because Sakurai suggests that each handpiece requires a different frequency sweep range (column 1, lines 31-47) and excitation current (column 9, lines 41-56) based upon the specific makeup of the device being used. Therefore one with ordinary skill in the art would select whatever range is required for the

user's specific device, such as 50 to 60 kHz or 5mA to 50mA, as necessary to implement the specific device in its required operation. (See also, for example, U.S. Patent No. 6,391,042 to Cimino, column 1, lines 28-37, U.S. Patent No. 5,406,503 to Williams Jr. et al., column 3, lines 50-60, and U.S. Patent No. 6,387,109 to Davidson et al., column 5, lines 6-26, which teach different ultrasonic devices requiring different frequency ranges and excitation currents for their individual operation.)

9. Claims 46 and 47, as may best be understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai et al. in view of Senda et al. and further in view of U.S. Patent No. 4,628,397 to Gareis et al.

As noted above, the invention or Sakurai and Senda teaches many of the features of the claimed invention and while the invention of Sakurai and Senda does teach performing a comparison between obtained impedance magnitude data and a known value to determine whether the impedance data is within acceptable limits, the combination does not explicitly state that the comparison is to be performed continuously.

Gareis teaches protected input/output circuitry for a programmable controller including means for sensing a current signal and continuously comparing the current signal to a known value to determine whether the current signal is within acceptable limits (abstract).

It would have been obvious to one having ordinary skill in the art to modify the invention of Sakurai and Senda to explicitly state that the comparison is performed

continuously, as taught by Gareis, because Gareis suggests that the combination would have provided a near real-time indication of the current state and provided corresponding actions to be taken as soon as the monitored state exceeds a desired value, thereby preventing damage to the device caused by performing outside of the desired range of operation (column 3, lines 40-49).

Response to Arguments

10. Applicant's arguments with respect to claims 1-5, 7-21, 23-32, 46 and 47 have been considered but are moot in view of the new ground(s) of rejection.

The following arguments, however, are noted.

Applicant first argues that "A drive signal is created by a drive system that creates the signal at a particular frequency and power. This drive system contains a microprocessor to monitor the power and vibration of frequencies using, for example, phase correction algorithms. The drive system sweeps the drive signal until a frequency lock is detected. Further, the drive system continuously sweeps to adjust the drive signal to get a frequency lock. A continuous sweep is important because as the hand piece/blade operates, it heats up. Heat causes the resonance point to shift downwards in frequency. The drive system must continuously sweep for the frequency lock or the hand piece/blade will cease to operate. *See*, for example, Specification page 12, lines 12-19, page 14, lines 14-26 and page 15, lines 8-24. Thus, a 'drive signal' as claimed must come from a 'drive system' and is not just a power impulse from a generator. Claims 1 and 17 recite that the hand

piece/blade is being continuously driven <u>by the drive signal</u> while the impedance data is being taken."

The cited sections of the specification state:

"In other words, in the frequency range of approximately 1,000 Hz, centered around the resonance frequency of an unbroken blade, the same type of broken blade will exhibit one impedance sweep characteristic at a low voltage excitation of the drive transducer and another at a high voltage excitation level. In contrast, an unbroken blade exhibits the same impedance at both excitation levels, as long as the impedance measurement is performed quickly enough, or at a low enough displacement level such that the transducer or the blade does not overheat. Heat causes the resonance point to shift downwards in frequency. This heating effect is most prevalent when the magnitude of the excitation frequency approaches the resonance frequency due to gunk" (page 12, lines 12-19).

"As illustrated in more detail in FIG. 5, the ultrasonic hand piece 30 houses a piezoelectric transducer 36 for converting electrical energy to mechanical energy that results in longitudinal vibrational motion of the ends of the transducer. The transducer 36 is in the form of a stack of ceramic piezoelectric elements with a motion null point located at some point along the stack. The transducer stack is mounted between two cylinders 31 and 33. In addition a cylinder 35 is attached to cylinder 33, which in turn is mounted to the housing at another motion null point 37. A horn 38 is also attached to the null point on one side and to a coupler 39 on the other side. Blade 32 is fixed to the coupler 39. As a result, the blade 32 will vibrate in the longitudinal direction at an ultrasonic frequency rate with the transducer 36. The ends of the transducer achieve maximum motion with a portion of the stack constituting a motionless node, when the transducer is driven with a current of about 380mA RMS at the transducers' resonant frequency. However, the current providing the maximum motion will vary with each hand piece and is a valve stored in the non-volatile memory of the hand piece so the system can use it" (page 14, lines 14-26).

"The system which creates the ultrasonic electrical signal for driving the transducer in the hand piece is illustrated in FIGS. 6(a) and 6(b). This drive system is flexible and can create a drive signal at a desired frequency and power level setting. A DSP 60 or microprocessor in the system is used for monitoring the appropriate power parameters and vibratory frequency as well as causing the appropriate power level to be provided in either the cutting or coagulation operating modes. The DSP 60 or microprocessor also stores computer programs which are used to perform diagnostic tests on components of the system, such as the hand

piece/blade. For example, under the control of a program stored in the DSP or microprocessor 60, such as a phase correction algorithm, the frequency during startup can be set to a particular value, e.g., 50 kHz. It can than be caused to sweep up at a particular rate until a change in impedance, indicating the approach to resonance, is detected. Then the sweep rate can be reduced so that the system does not overshoot the resonance frequency, e.g., 55 kHz. The sweep rate can be achieved by having the frequency change in increments, e.g., 50 cycles. If a slower rate is desired, the program can decrease the increment, e.g., to 25 cycles which both can be based adaptively on the measured transducer impedance magnitude and phase. Of course, a faster rate can be achieved by increasing the size of the increment. Further, the rate of sweep can be changed by changing the rate at which the frequency increment is updated" (page 15, lines 8-24).

The Examiner asserts that the cited portions of the specification indicate that, if desired, a program can cause a sweep to determine a change of impedance. With respect to the claimed limitations for the drive signal, however, parent claims 1 and 17, only require "a drive signal having an initial drive current and an initial drive voltage". Any other limitations regarding the specifics of the drive system are not read into the claimed limitations for a method that only specifies "applying a drive signal having an initial drive current level and an initial drive voltage level to an ultrasonic hand piece/blade".

The Examiner also asserts that while the invention of Sakurai does include a "drive circuit 5" that is controlled by a "switch drive circuit 8", the impedance detection circuit "11" also contains a power supply "12" that continuously applies a drive signal during the impedance measurement. Specifically, Sakurai states:

> "With the switch 13 turned ON, a voltage on the AC power source 12 is created across the output terminals 11a, 11b via the current detector 14. The voltage is applied to the ultrasonic vibration element 2 via the normally closed contacts of the switches 7a, 7b in the changeover circuit 6. As a result, a current I flows through the ultrasonic vibration element 2 and detected by the current detector 14. The result of detection is sent to the computing section 16. With the

switch 13 turned ON, a voltage V on the AC power source 12 is detected by the voltage detector 15 and a result of detection is sent to the computing section 16. The computing section 16 divides the voltage V by the current I to find an impedance Z of the ultrasonic vibration element 2 at step S3. The impedance Z thus found is fed to the CPU 10. The CPU 10 ascertains whether the impedance Z is within a predetermined range, such as $Z_1 \leq Z \leq Z_2$, at step S4. Here Z_1 and Z_2 denote the setting values. If the impedance Z is a proper value, the CPU 10 determines that the ultrasonic vibration element 2 is good at step 5" (column 4, lines 17-34)."

Therefore, the Examiner asserts that the AC power source continuously applies a signal having an initial drive current level and an initial drive voltage level to an ultrasonic hand piece/blade while the impedance data is being taken and therefore meets the limitation for a hand piece/blade being continuously driven by a drive signal while the impedance data is being taken.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

U.S. Patent No. 6,391,042 to Cimino teaches a pulsed ultrasonic device and method as well as the conventional operating range of 20kHz to 60kHz.

U.S. Patent No. 5,406,503 to Williams Jr. et al. teaches a control system for calibrating and driving ultrasonic transducers including a power amplifier and transformer section that provides a maximum driving voltage of about 380 volts RMS with a maximum current of about 10 mA RMS.

U.S. Patent No. 6,387,109 to Davidson et al. teaches methods and a device for improving blood flow to the heart of a patient including a generator that applies a

specific current to acoustically vibrate an assembly in the range of 20kHz to 100 kHz, preferably, 54 kHz to 56 kHz.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. West whose telephone number is (703)308-1309. The examiner can normally be reached on Monday through Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (703)308-1677. The fax phone number

for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0956.

jrw
June 8, 2005

Marc Hoff
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